

DENTAL CT/3D CONE BEAM AND THE CON: UNNECESSARY GOVERNMENT REGULATION

- Michigan is one of only two states in the country that regulate the Dental CT under Certificate of Need (CON). *See the attached chart.*
- On average, a Dental CT costs \$90,000 - \$100,000.
- The application process, while minimally improved, is still difficult. *See the attached set of instructions from the State of Michigan CON website.*
- The fee that must be paid to the state when applying for a CON is \$3000. Many dentists, not having the time or expertise to go through this process, hire consultants to help them. This can add another \$3000 - \$5000 to the cost of obtaining a CON.
- The Dental CT, if removed from CON regulation, would continue to be regulated by the Michigan Radiation Safety Section in the Department of Licensing and Regulatory Affairs. Thus insuring patient safety.
- Radiation exposure from a Dental CT is just slightly higher than that of a traditional x-ray machine, and still within the minimal exposure range. *See attached chart.*
- The slightly higher exposure rate for the Dental CT is offset by the increased clarity of the picture, which helps the dentist to better avoid hitting nerves and sinus cavities. Thus allowing for safer treatment and less pain to the patient.
- The Michigan Dental Association (MDA) has tried on several occasions to deregulate or modify CON regulation of the Dental CT through the CON Commission, but has not been successful.
- The Dental CT is quickly becoming the standard of care in dentistry around the country. Michigan residents should not be denied the benefits of the Dental CT.
- Some insurance companies cover the Dental CT, but the service is optional in most cases for the patient. The cost of a Dental CT scan is on average \$150-\$250.

States that Regulate CT Scanners:

Alaska

- Exempts CT scanners under \$1,400,000 or Private Practices

Connecticut

- Exempts acquisition of cone-beam dental imaging equipment that is to be used exclusively by a state licensed dentist.

Hawaii

- Exempts dentists from purchases less than \$1,000,000 for new medical equipment or \$400,000 for used medical equipment

Iowa

- Exempts private practice dentists

Kentucky

- Exempts private practice dentists

Maine

- Exempts purchases less than \$3,200,000

Michigan

- All CT scanners require Certificate of Need

Missouri

- Exempts purchases less than \$1,000,000

New York

- Exempts private practices from Certificates of need

North Carolina

- Exempts CT scanners less than \$750,000

Rhode Island

- All CT scanners require a Certificate of Need

Vermont

- Exempts CT scanners less than \$1,000,000

Virginia

- Dentists are not subject to Certificate of Need requirements

West Virginia

- Exempts dental CT scanners less than \$2,000,000

Instructions for Dental Computed Tomography (CT) Applications Michigan Department of Community Health Certificate of Need (CON)

Obtaining CON approval for a dental CT service involves the following steps:

1. Register for a CON e-Serve Username and Password (Note: the steps below can be submitted in paper format, if desired but not recommended)
2. Prepare and file a Letter of Intent
3. Prepare and file a CON application
4. If CON application is approved, then follow-up with Project Implementation Progress Report (PIPR), form number CON-1300, 11 months after CON approval or upon implementation of the project, whichever is sooner.

Please note: You must choose the specific make and model of the dental CT scanner you wish to operate. If the make/model changes after the CON application has been submitted, but before a decision has been issued, please contact the Department immediately. If a change is made after CON approval, an amendment request must be filed, which can be completed through the CON e-Serve online system.

Michigan's CON program has developed an online system (DCH CON e-Serve) for preparing, filing, and tracking CON applications and projects. A potential applicant must first register to use the system by completing the steps located at:

http://www.michigan.gov/mdch/0,4612,7-132-2945_5106-165238--,00.html .

Once your registration is complete and a username and password have been assigned, you will be able to login to prepare and file your Letter of Intent and CON application.

Letter of Intent

Section 1 – Provide the facility name and address of the location where the dental CT will be located. Also, enter applicant's Federal ID; if not available, leave blank.

Section 2 – Provide the corporate name of the applicant entity as it is registered with the Corporations Division. Do not enter the personal name of the doctor, if that is not the name of the corporate entity.

Section 3 - Provide contact information for the person who will be responsible for completing and filing the CON application.

Section 4 – Facility type will be 'Other' and specify 'Dentist Office'.

Section 5 – Provide a brief title for the project, e.g., initiate dental CT scanner service.

Section 6 – Service change table; enter 'Dental CT Scanner' as service type and select 'New' as type of change.

Section 7 – Bed information is 'Not applicable'.

Section 8 – Select appropriate line items with the costs for implementing the dental CT scanner. Report the cost of dental CT equipment as 'covered clinical equipment'. Also, report any

construction/renovation as 'new construction or renovation-clinical'. If the dental practice will lease space in a medical office building, then provide space lease cost for the duration of the lease as 'space lease cost'.

Section 9 – Provide source of funds for the project. Must equal total project cost.

Section 10 – Select 'No'.

Section 11 – Select project type 'Initiate covered clinical service'. If the project involves any renovation or new construction, then select additional types accordingly.

Section 12 – Provide a narrative description of the project including details for the services proposed, location, and square footage for lease or construction/renovation.

CON Application Forms

No#	Form No.	Description	Notes
1	CON-100-Instructions	Application Information and Instructions	No need to file with CON application
2	CON-100	Application for CON	
3	CON-105	Project Summary	Read only form; no need to enter data
4	CON-200-A	Review Standards Instructions	No need to file with CON application
5	CON-200	Responses to Section 22225	
6	CON-300	Project Description	
7	CON-600	Project Personnel Need	
8	CON-212	CT Scanner Review Standards	
9	CON-706	CT Scanner Utilization Report	Not online; download from web site** and submit by mail/e-mail
10	CON-706-A	CT Scanner Physician Commitment Form	Not online; download from web site and submit form with original signature
11	CON-1000	Equipment Report	
12	CON-1001	Major Equipment Report	
13	CON-1100	General Financing Questions	
14	CON-1118	Revenue and Expense Statement - Other	
15	CON-1200	Financed Projects	Only for financed project (loan, mortgage, etc.)
16	CON-1202	Debt Service Coverage	Only for financed project (loan, mortgage, etc.)
17	CON-1203	Amortization	Only for financed project (loan, mortgage, etc.)

**** Web site:** www.michigan.gov/con , select 'Electronic Forms' from 'Find it Now' drop down; or 'DCH CON e-Serve Online Application' from 'Online Tools' drop down.

CON Application Required Documents

1. Copy of applicant's proposed purchase and/or lease agreement(s), as applicable.
2. Copy of vendor quotation(s) for the Applicant signed by vendor - no more than six months old from the date application is submitted.
3. Verification of Medicaid Participation.
4. Copy of audited financial statements. If not available, provide unaudited current financial statements including a balance sheet, income statement, statement of cash flows and any notes. New entities must provide a current balance sheet, a projected income statement for the first year of operations, a projected statement of cash flows for the first year of operations, and any notes to the financial statements.

CON-100

If submitting through the online e-serve system, much of this form will be automatically populated from the Letter of Intent.

CON-200, Responses to Part 222 (CON Statute)

An applicant needs to respond to the following sections:

Section 22225(1) – State that the applicant has demonstrated compliance with the CON Review Standards for CT Scanner Services.

Section 22225(2)(a) – Provide an alternative to the chosen project that was considered, (i.e., continuing to use a panoramic unit, or refer patients for a medical CT scan) and describe why the chosen project is the most efficient and effective method of meeting the unmet need. Include estimated cost of alternative considered and justification for choosing proposed project, including cost perspective.

Section 22225(2)(b) – Refer to the responses in form CON-1100.

Section 22225(2)(c) – Respond with the wording provided in the online form.

22225(2)(e) – If applicant is a for-profit organization then check the box 'Not Applicable/No Response Required'.

CON-212, CT Scanner Review Standards

An applicant needs to respond to the following sections only:

Section 4:

- 4(1) – Respond with a statement agreeing to this provision.
- 4(2) – Provide the peak power of the proposed dental CT scanner and provide documentation (i.e. manufacturer specifications).
- 4(3) – Respond with a projection of at least 200 scans per year (this number is also verified through form CON-706).
- 4(4) – List the dentists and/or staff members who have been trained to operate the dental CT scanner and provide documentation of the training. This training must be completed and documentation submitted at least 30 days prior to your decision date.

4(5) - List the dentist(s) who will interpret the images generated by the proposed dental CT scanner and provide documentation of the training.

4(6)(a)- Respond with 'Not Applicable'.

4(6)(b)- Respond with 'Not Applicable'.

Section 19 – Describe and provide documentation that the applicant has enrolled as a Medicaid provider. Proof can include a printout of the CHAMPS system that lists the name and NPI number of the applicant and/or dentist.

Section 20:

20(2) – Respond with 'Not applicable'.

20(3)- Respond with 'Not applicable'.

20(4) – Respond with 'Not applicable'.

20(5) – Respond with 'I Agree'.

20(6)- Respond with 'Not applicable'.

20(7)- Respond with 'Not applicable'.

20(8)- Respond with ' Not applicable'.

20(9)- Respond with the wording provided 'By submission of this electronic application, I certify as the authorized agent that the applicant will abide by the agreements and assurances required by this Section.'

Section 23:

23(1) – Respond with 'Not applicable'.

23(2) – Respond with this statement 'Refer to the attached spreadsheet or billing records'.

Provide documentation (HIPAA compliant spreadsheet or billing records) that at least 200 dental procedures* were performed within a recent 12-month period by the dentists committing referrals to the proposed project.

23(3)(a),(b),(c) – Respond with 'Not applicable'.

* Dental procedures are defined as dental implants, wisdom teeth surgical procedures, mandibular or maxillary surgical procedures, or TMJ evaluations

CON-300

This form is automatically populated from the Letter of Intent. However, please be sure it includes at least the following information:

- Type of dental CT unit being purchased
- Description of area where dental CT will be installed, including approximate square footage
- Description of any renovations or construction required for installation

CON-600, Project Personnel Need

Fill out the personnel chart to accurately reflect the staffing level of the dental practice and any additional FTEs required for this project.

CON-706, CT Scanner Utilization Report

On page 1, project for the 2nd year of operation (column c) at least 200 Head Scans Without Contrast for Adults. Ignore the Pediatric section because all dental scans have a conversion factor (column a) of 1.0. On page 2, carry the number from page 1 over to the last row, column c.

CON-706-A, CT Scanner Physician Commitment

On page 1, fill out every box in the section below INSTRUCTIONS and provide a radius map showing the location of the proposed dental CT service and the location of the referring dentist (the locations should be within 20 miles for urban sites, 75 miles for rural sites). The next box should be signed by the referring dentist and must include the license number and date of signature. The signature must happen after the rest of the form has been completed in its entirety.

Note: Must provide 1 signed form for each dentist committing dental procedures to the application.

On page 2, the bottom section is the only part of this page to be filled out. In the left-hand column provide the historical number of dental procedures performed in a recent 12-month period by the referring dentist. In the right-hand column provide the number of CT scans to be referred by the committing dentist to the proposed service. This number must be equal to or lower than the number in the left-hand column. The total number of referrals (right-hand column) from all commitment forms combined must total at least 200 in order to be approved.

CON-1000, Equipment Report

Item 1 – Check 'yes' if initiating a new dental CT scanner and describe the location in the space below.

Items 2 through 7 – These are for projects involving the replacement of a dental CT scanner.

Item 8 – Estimate the useful life of the proposed dental CT scanner.

Item 9 - Involves depreciation of the proposed dental CT scanner, usually it is 7 years.

Item 10 - Involves method for depreciation of the proposed dental CT scanner, usually it is 'Straight Line'.

Item 11 – Describe any construction or renovation involved in the project, i.e., lead-lined.

Item 12 – List '0' existing dental CT scanners and '1' proposed dental CT scanners.

Items 13 - Describe the advantage of dental CT over currently used imaging equipment.

Items 14 through 18 – Largely self-explanatory, provide brief descriptions to answer the questions. If an item is not applicable, type so.

CON-1001, Major Equipment Report

List the make, model and cost of the proposed dental CT scanner. Also, provide basis for the estimated cost using the number keys found below. For Type column, use 'D'.

CON-1100, Financial Information

Item 1 – Provide 12-month reporting year and select 'calendar' or 'fiscal'.

Item 2 – No response required.

Item 3 – Self-explanatory.

Item 4 – No response required.

Item 5(a) – Provide at least one alternative to the chosen project and the capital cost of the alternative (i.e., continuing to use a panoramic unit, refer patients for a medical CT scan or purchase a full body medical CT scanner) and the chosen project.

Item 5(b)(i) – Submit audited or unaudited financial statement for the applicant entity. No response required for item 5(b)(i)(b).

Item 5(b)(ii) – State that the project will break even within 3 years. Must be consistent with the amounts reported in form CON-1118 (revenue and expense form).

Item 5(c) – Provide chosen financial method for the project, e.g., cash or mortgage/loan. Provide rejected financial method for the project, e.g., cash or mortgage/loan.

Item 5(d) – If source of fund is not loan or mortgage, then no response is required to this item.

Item 5(e) – Competitive bid section; select 'Yes' and 'I agree'.

Project costs – Select appropriate categories for your project. If project involves construction or renovation, enter square footage in the 3rd column of the table. Report the cost of dental CT as 'covered clinical equipment'. Also, report any construction/renovation as 'new construction or renovation-clinical'. If the dental practice will lease space in a medical office building, then provide space lease cost for the duration of the lease as 'space lease cost'.

Source of funds - Provide source of funds for the project. Must equal total project cost. Common source of funds are unrestricted cash, mortgage/loan, capital/operating lease.

Lease arrangement – If project involves lease of the dental CT scanner or lease of space for the dental office, then provide the details of each lease. Usually dental CT scanner lease is reported under 'capital' lease and office space lease is reported under 'operating' lease.

Depreciation and amortization schedule - Involves method for depreciation of the proposed dental CT scanner, usually it is 'Straight Line' method over 7-year period.

Sources of revenues – Provide appropriate revenue category and percentage, which must equal 100%.

CON-1118, Statement of Revenue and Expenses

Only fill out the line items that apply to the dental practice, rest can be left blank.

CON-1200, Financed Projects

This form is required only if the project involves a loan. Provide details as required by the form.

CON-1202, Debt Service Coverage Report

This form is required only if the project involves a loan. Provide details as required by the form.

CON-1203, Projected Debt Service Requirements

This form is required only if the project involves a loan. Provide details as required by the form. Applicant may submit a separate amortization schedule instead of completing the bottom section of this form.

CON-1300 (Project Implementation Progress Report)

This form is completed 11 months following the CON approval or at the time the project is implemented, whichever comes first.

If the project is not completed within 11 months, then please fill out the following sections (use CON approval letter to obtain most of this information):

- Top of page 1, applicant information
- Project description
- Top of page 2
- Provide copy of purchase/lease agreement for dental CT unit
- Project details, only if any aspects of your project have changed, including a change in the specific dental CT unit you are purchasing.
- For the remaining sections on page 2, 3, and 4, please complete the "Approved" columns only with information from the CON approval letter. "Final" column should not be completed until the project is 100% complete.

When the project is 100% complete (when your dental CT scanner is installed and operational), please complete the following sections:

- All of page 1
- Provide copy of vendor purchase order/lease agreement for the dental CT unit
- Provide copy of Radiation Safety Certificate
- Obtain copy of Patient Log for your records, but include date of 1st billable dental CT scan at the bottom of page 1
- Project details, only if any aspects of your project have changed, including a change in the specific dental CT unit you are purchasing.
- For the remaining sections on page 2, 3, and 4, please complete the "Approved" columns with information from your CON approval letter (or amended approval letter if you have had to file an amendment request) and complete the "Final" column with information about your project as implemented.
- Please note that final project costs exceeding approved budget by more than 15% (assuming project costs do not exceed \$1 million) will require an amendment request.

Tests by the radiation dose

Procedure	Radiation dose (millisievert) ^{1,2}	Comparable exposure from natural sources, such as radon	Should you get it?
Minimal dose: Less than 0.1 millivert			
X-ray of teeth (bitewing)	0.005	less than 1 day	Most people need one only every 24 to 36 months.
X-ray of teeth (full mouth)	0.010	about 1 day	Many people can go a decade between exams.
Cone-beam CT of jaw and teeth	0.06	7 days	Rarely needed for most orthodontic procedures.
Low dose: 0.1 to 1 millivert			
X-ray of chest (two views)	0.1	12 days	Presurgery X-rays needed only for people with a history of lung or heart disease (or those at risk) or before chest surgery.
Mammogram	0.4	7 weeks	Needed every two years for women ages 50 to 74.
Medium dose: 1 to 10 milliverts			
X-ray of spine	1.5	6 months	Rarely needed in first month back pain.
CT of head	2	8 months	Not needed for most head injuries. CTs usually aren't needed for a concussion.
CT of spine	6	2 years	Rarely needed in first month of back pain.
High dose: 10 milliverts and over			
CT colonoscopy	10	3 years	Not as accurate as standard colonoscopy.
CT of abdomen and pelvis	10	3 years	For possible appendicitis or kidney stone, ask whether ultrasound can be used.
CT angiography (of the heart)	12	4 years	1 in every 1,300 60-year-olds may get cancer as a result, so it probably shouldn't be used for screening.

CT of abdomen and pelvis repeated with and without contrast	20	7 years	"Double scans" are rarely necessary; fewer than 5 percent of patients should receive one.
PET with CT	25	8 years	It exposes patients to very high radiation doses, so make sure that it is really necessary.

1. Doses are typical values for an average-sized adult. The actual dose can vary substantially depending on a person's size as well as on differences in imaging. **2.** For every 2,000 people exposed to 10 millisieverts of radiation from a ct scan, one will develop cancer, according to the Food and Drug Administration.

Editor's Note:

This article also appeared in the March 2015 issue of *Consumer Reports* magazine.

<http://www.consumerreports.org/cro/magazine/2015/01/the-surprising-dangers-of-ct-sans-and-x-rays/index.htm#>